UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION
PREVENTION

MEMORANDUM

DATE: October 31, 2012

SUBJECT: Efficacy Review for Hitman;
EPA File Symbol 9402-RU
DP Barcode: D405017

FROM: Lorilyn M. Montford LM 10/31/12
Efficacy Evaluation Team
Antimicrobials Division (7510P)

THRU: Emily Mitchell, Chief EM 10/31/12
Product Science Branch
Antimicrobials Division (7510P)

TO: Marshall Swindell, PM33/Demson Fuller
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: Kimberly-Clark Global Sales, Inc.
2100 Winchester Road, Neenah, WI 54956

FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Hydrogen Peroxide	3.30%
Didecyldimethylammonium carbonate and didecyldimethylammonium bicarbonate	1.38%
Inert Ingredients	95.32%
Total	**100.00%**

I BACKGROUND

The product, Hitman (EPA File Symbol 9402-RU), is a new product. The applicant requested to register the product for use as a bactericide (disinfectant, virucide, and fungicide), sanitizer (non-food contact sanitizer and non-food contact residual self-sanitizer), mildewstat, and deodorizer for use on hard, non-porous surfaces for residential use only. The product is not intended for use in institutional, industrial or commercial establishments. Proposed label directions indicate that the product is a one-step disinfectant which infers that the product is effective in the presence of an organic soil load. The applicant previously submitted efficacy data to support the new product, however, the efficacy data for *Staphylococcus aureus* failed in the original submission (DP Barcode: D399989, dated June 20, 2012). The applicant has resubmitted data with this submission for *Staphylococcus aureus* only. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121 and ATL located at 1304 W. Industrial Blvd, in Round Rock, TX, 78681.

This data package contained a letter from the registrant's representative (dated August 10, 2012), Form 8570-1 (Application for Pesticide), Data Matrices, one study (MRID 48907001), Statement of No Data Confidentiality Claim, Good Laboratory Practice statement, and the proposed label.

II USE DIRECTIONS

The product is designed for sanitizing (hard, non-porous and soft surfaces) and disinfecting hard, non-porous surfaces including: desktops, doorknobs, faucets, chairs, cell phones, computers, soap dispensers, vanities, telephones, shower walls, kitchens, bathrooms, light switches, refrigerator exteriors, garbage cans, mouse pads, offices, laundry rooms, toilets, range hoods, and stove tops. The product is also for use (as a sanitizer) on washable soft surfaces such as, drapes, gym bags, diaper bags, upholstery, uniforms, shower curtains, pillows, sleeping blankets, sofas, oven mitts and rugs. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: aluminum, brass, ceramic, Corian ®, glass, granite, laminate, stainless steel, vinyl, glazed porcelain, painted surfaces, polycarbonate, polypropylene, polyurethane varnish, and silicone rubber. Directions on the proposed label provide the following information regarding use of the product:

Disinfectant: To disinfect hard, non-porous surfaces, spray 6-8 inches from surface until thoroughly wet. Let stand for 5 minutes. Wipe dry. Remove heavy soil prior to disinfection. To disinfect Norovirus, let stand for 6 minutes.

Non-Food Contact Sanitizer: For hard, non-porous, non-food contact surfaces, spray 6-8 inches from surface until thoroughly wet. Let stand for 15 seconds. Wipe dry. Remove heavy soil prior to sanitization.

Residual Self-Sanitizer: To sanitize for 24 hours against *Staphylococcus aureus*, *Enterobacter aerogenes*, and Community Acquired Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) on hard, non-porous surfaces. Spray 6-8 inches from surfaces until thoroughly wet. Let stand for 5 minutes. Wipe dry. This product can be removed with soap and water. Repeat residual self-sanitizing directions to maintain 24 hours sanitization.

Soft Surface Sanitizer: Test a hidden section of fabric. Spray 6-8 inches from surface until moderately damp. DO NOT SATURATE. Fabric must remain wet for 30 seconds. Let air dry.

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III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). If the product is intended to be represented as bactericidal in the presence of organic soil (one-step), an appropriate organic soil, such as 5 percent blood serum, should be included with the bacterial inoculum. To support products labeled as "disinfectants," killing on 59 out of 60 carriers in $\leq$ ten minutes is required to provide effectiveness at the 95% confidence level. In addition, per the 2009 AOAC revisions for the Use-Dilution Method, the mean log density for *S. aureus* and *P. aeruginosa* is to be at least 6.0 (corresponding to a geometric mean density of 1.0×10^6).

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 48907001, "AOAC Germicidal Spray Method", Test Organism: *Staphylococcus aureus* (ATCC 6538), for Hitman Spray, by Joshua Luedtke, M.S. Study conducted at ATS Labs located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121. Study completion date – August 6, 2012. Project No. A13812.

This study was conducted against *Staphylococcus aureus* (ATCC 6538), One lot of product (Lot # SA1255BLE), Hitman Spray, was tested using the AOAC Germicidal Spray Method, published by Association of Official Analytical Chemists, Method # 961.02 (2000). From a stock slant, an initial tube (10 mL) of culture broth was inoculated. The culture was termed the "initial broth suspension". From this suspension a minimal of three daily transfers were made using 1 loopful (10µL) of culture into 10 mL of culture media were performed on consecutive days prior to use in testing procedure. The appropriate growth medium was used for the test organism and subcultured using daily transfers. A 48-54 hour broth culture incubated at 35-37°C was prepared. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris. The removed portion was transferred to a sterile vessel and used for testing. However, prior to use the final test culture was thoroughly mixed. A 0.10 mL aliquot of fetal bovine serum was added to 1.90 mL of each broth culture to yield a 5% organic soil load. Individual glass slide carriers were each inoculated with 10.0 µL of

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culture using a calibrated pipettor. The inoculum was uniformly spread over the entire surface of the slide contained in the Petri dish. The dish was covered immediately, and the procedure repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C and 52% relative humidity. Test carriers were sprayed in a horizontal position at a distance of 6-8 inches using 3 sprays. The treated carrier was held at room temperature (21°C) and a relative humidity of 63% for a 3 minute and 30 second contact time. At the end of the exposure time, excess liquid was drained off the carrier. The treated carriers were then transferred at staggered intervals to 20 mL aliquots of Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.01% Catalase. The carriers were transferred from primary to secondary subcultures containing the same amount of Letheen Broth combination. All subcultures and controls were incubated for 48±4 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. Controls included those for purity, organic sterility, carrier sterility, neutralization confirmation, viability and carrier population.

Note: Efficacy data was reported to be generated at the lower certified limits, consistent with the CSF.

V RESULTS

MRID	Test Organism	Number of Carriers		CFU/Carrier (Log)
		Exposed	Showing Growth	
48907001	*Staphylococcus aureus*	1° 60	1° 0	4.0×10^5
		2° 60	2° 0	

1° = primary subculture
2° = secondary subculture

VI CONCLUSIONS

1. The submitted efficacy data (MRID 48907001) supports the use of the product, Hitman Spray, as a disinfectant against *Staphylococcus aureus*, on hard non-porous surfaces in the presence of a 5% organic soil load for a contact time of 3 minutes.

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of lots. Neutralizer effectiveness showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

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VII RECOMMENDATIONS

1. The proposed label claims that the product, Hitman Spray, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 3 minutes:

Staphylococcus aureus (ATCC 6538)

Note: The additional claims for the proposed product, Hitman Spray, against the listed